(C) detecting synthesis of protein.

REMARKS

Reconsideration of this application is respectfully requested.

With entry of this amendment, claims 1-6, 8-10, 12-19, 27-29, and 31-43 are pending in this application. Support for the amendments to the claims is found throughout the application, such as at page 5, lines 12-15; page 6, lines 4-15 and 22-38; Table 2 at page 48; and in the original claims as filed. New claim 41 is the same as cancelled claim 26, except that claim 41 depends from claim 28 instead of claim 25. New claim 42 is the same as cancelled claim 11, except that claim 42 depends from claim 40 instead of claim 1.

Because the amended and new claims are supported by the specification, no new matter enters by amendment, and entry of this amendment is proper.

Response to Restriction Requirement

In a restriction requirement dated December 18, 2002, the Examiner required restriction under 35 U.S.C. § 121 between Group I, claims 1-2, drawn to nucleic acids; Group II, claims 3-6 and 8, drawn to methods of detecting mycobacterial species by nucleic acid amplification; Group III, claim 9, drawn to kits comprising primers; Group IV, claim 10, drawn to methods of nucleic acid amplification; Group V, claims 11, 14-15, and 17, drawn to polypeptides, antibodies, and kits comprising polypeptides and antibodies; Group VI, claims 12-13 and 27-33, drawn to methods of detecting antibodies; Group VII, claim 16, drawn to methods of detecting protein; Group VIII, claim

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18 and 19, drawn to a vaccine; and Group IX, claims 20-23 and 25-26, drawn to methods of detecting mycobacterial species by restriction digestion.

The Examiner further required an additional election if Group I, V, VI, VII, or VIII were elected. In particular, the Examiner required that a single molecule recited in the claims of these groups be elected. The Examiner noted, however, that if Group I is elected, one of the combinations or groups of molecules recited in claim 2 could be elected, instead of electing a single molecule recited in claim 1.

Applicants provisionally elected to prosecute Group I, claims 1-2, drawn to nucleic acids, with traverse. Applicants also provisionally elected to prosecute the molecules of Group E in claim 2 ("RD9: *cobL*, Rv2073c, Rv2074, Rv2075c"), with traverse.

The restriction and election requirements are based on the Examiner's contention first, that "[t]he inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features." (Office Action at page 2, item 2.) The Examiner goes on to contend that (1) "a shared technical feature [in the sequences of Group I is] that [they] are 'deleted from the genome of *M. bovis* BCG/*M. bovis* and present in the genome of *M. tuberculosis*';" (2) "such sequences were known in the art at the time the invention was made" (for which the Examiner cites Brosch et al.); and (3) "[a]s molecules meeting the limitations of Group I do not make a contribution over the art, this feature cannot constitute a special technical feature as defined by PCT Rule 13.2, and unity of invention is therefore lacking." (Office Action at item 2, paragraph bridging pages 2-3.) Applicants respectfully traverse.

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Claims 1 and 2, as amended, and new claims 34-40, which correspond to Group I, recite "A nucleotide or polynucleotide sequence deleted from the genomes of *M. bovis* BCG, *M. bovis*, and *M. microti* OV254, and present in the genome of *M. tuberculosis*." Brosch et al. does not disclose a nucleotide or polynucleotide sequence deleted from the genome of *M. microti* OV254. Therefore, Brosch is not evidence that sequences defined by the claims of Group I were known in the art at the time the invention was made, as alleged by the Examiner. Therefore, in view of the amendment, there is no basis for the allegation that molecules meeting the limitations of Group I do not make a contribution over the art, no basis for the allegation that no feature of the claims of Group I constitutes a special technical feature as defined by PCT Rule 13.2, and no basis for the allegation that unity of invention is lacking. Applicants respectfully submit that, in view of these circumstances, there is no basis to support a requirement for Restriction or Election and that, therefore, the requirements for Restriction and Election cannot be sustained as to the amended claims.

Accordingly, applicants respectfully request the timely examination and allowance of the pending claims 1-6, 8-10, 12-19, 27-29, and 31-43.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: June 4, 2003

By: _____
Kenneth J. Meyers
Reg. No. 25,146

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
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APPENDIX

1. (Three times amended) A nucleotide or polynucleotide sequence deleted from the genomes of *M. bovis* BCG[/], *M. bovis*, and *M. microti* OV254, and present in the genome of *M. tuberculosis* [or a nucleotide or polynucleotide sequence of the following ORFs and genes: Rv2346c, Rv2347c, Rv2348c, *plcC*, *plcB*, *plcA*, Rv2352c, Rv2353c, Rv3425, Rv3426, Rv3427c, Rv3428c, Rv1964, Rv1965, *mce3*, Rv1967, Rv1968, Rv1969, *lprM*, Rv1971, Rv1972, Rv1973, Rv1974, Rv1975, Rv1976c, Rv1977, *ephA*, Rv3618, Rv3619c, Rv3620c, Rv3621c, Rv3622c, *lPqG*, *cobL*, Rv2073c, Rv2074, Rv2075, *echAl*, or Rv0223c].

2. (Three times amended) The nucleotide or polynucleotide sequence[s as claimed in] according to claim 1, wherein the nucleotide or polynucleotide sequence is [grouped together in] present in nucleotide region[s] RD5 [to], RD6, RD7, RD8, RD9, or RD10 [according to the following distribution:

(A) RD5: Rv2346c, Rv2347c, Rv2348c, *plcC*, *plcB*, *plcA*, Rv2352c, Rv2353c;

(B) RD6: Rv3425, Rv3426, Rv3427c, Rv3428c;

(C) RD7: Rv1964, Rv1965, *mce3*, Rv1967, Rv1968, Rv1969, *lprM*, Rv1971, Rv1972, Rv1973, Rv1974, Rv1975, Rv1976c, Rv1977;

(D) RD8: *ephA*, Rv3618, Rv3619c, Rv3620c, Rv3621c, Rv3622c, *lpqG*;

(E) RD9: *cobL*, Rv2073c, Rv2074, Rv2075c; and

(F) RD10: *echAl*, Rv0223c].

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3. (Twice amended) A method for [the discriminatory detection and identification] discriminating [of] *M. bovis* BCG,[/] *M. bovis*, or *M. microti* OV254, from *M. tuberculosis* in a biological sample, the method comprising:

(A) isolating [the] DNA from the biological sample [to be analyzed] or produc[tion]ing [of a] cDNA from [the] RNA of the biological sample;

[(B) detecting the DNA sequences of [the] mycobacterium present in said biological sample;] and

([C]B) analyzing said DNA or cDNA sequences with the nucleotide [and] or polynucleotide sequence[s] as claimed in claim 1.

4. (Twice amended) The method as claimed in claim 3, wherein the [detection] analysis of the [mycobacterial] DNA or cDNA sequences is carried out using nucleotide sequences complementary to said DNA or cDNA sequences.

5. (Twice amended) The method as claimed in claim 3, wherein the [detection] analysis of the [mycobacterial] DNA or cDNA sequences is carried out by amplifying the sequences using primers.

6. (Twice amended) The method as claimed in claim 5, wherein the primers have a nucleotide sequence chosen from the group comprising SEQ ID No. 1, SEQ ID No. 2, SEQ ID No. 3, SEQ ID No. 4, SEQ ID No. 5, SEQ ID No. 6, SEQ ID No. 7, SEQ

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ID No. 8, SEQ ID No. 9, SEQ ID No. 10, SEQ ID No. 11, SEQ ID No. 12, SEQ ID No. 13, and SEQ ID No. 14, [SEQ ID No. 15, SEQ ID No. 16, SEQ ID No. 17, and SEQ ID No. 18] and wherein:

(A) the pair SEQ ID No. 1/SEQ ID No. 2 is specific for RD4;

(B) the pair SEQ ID No. 3/SEQ ID No. 4 is specific for RD5;

(C) the pair SEQ ID No. 5/SEQ ID No. 6 is specific for RD6;

(D) the pair SEQ ID No. 7/SEQ ID No. 8 is specific for RD7;

(E) the pair SEQ ID No. 9/SEQ ID No. 10 is specific for RD8;

(F) the pair SEQ ID No. 11/SEQ ID No. 12 is specific for RD9; and

(G) the pair SEQ ID No. 13/SEQ ID No. 14 is specific for RD10;

[(H) the pair SEQ ID No. 15/SEQ ID No. 16 is specific for RvD1; and

(I) the pair SEQ ID No. 17/SEQ ID No. 18 is specific for RvD2].

8. (Twice amended) A method for [the discriminatory detection and identification] discriminating [of] *M. bovis* BCG,[/]*M. bovis*, or *M. microti* OV254, from *M. tuberculosis* in a biological sample, wherein the method compris[ing]es:

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(A) bringing the biological sample [to be analyzed] into contact with at least one pair of primers as defined in claim 6, [the DNA contained in the sample having been, where appropriate, made accessible to the hybridization beforehand];

(B) amplifying the DNA of the mycobacterium; and

(C) visualizing the [amplification of the] amplified DNA fragments.

9. (Twice amended) A kit for [the discriminatory detection and identification] discriminating [of] *M. bovis* BCG,[/]*M. bovis*, or *M. microti* OV254, from *M. tuberculosis* in a biological sample, wherein the kit compris[ing]es:

(A) at least one pair of primers as defined in claim 6;

(B) reagents necessary to carry out a DNA amplification reaction; and

(C) components[, which make it possible to verify or compare the sequence, the size of] to characterize the amplified fragment by size and/or sequence[, or both the sequence and the size of the amplified fragment].

10. (Twice amended) A method of amplifying a DNA sequence from *M. bovis* BCG[/], *M. bovis*, *M. microti* OV254, or *M. tuberculosis*, wherein the method compris[ing]es hybridizing at least one [of the] pair of primers of claim 6 to the DNA sequence.

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12. (Twice amended) An *in vitro* method for [the discriminatory detection and identification] discriminating [*in vitro* of] antibodies directed against *M. bovis* BCG[/]*M. bovis*, or *M. microti* OV254, from antibodies directed against *M. tuberculosis* in a biological sample, wherein the method compris[ing]es:

(A) bringing the biological sample into contact with at least one product as defined in claim 11, and

(B) detecting the antigen-antibody complex formed.

13. (Three times amended) A method for [the discriminatory detection of] discriminating a vaccination with *M. bovis BCG*, *M. bovis*, or *M. microti* OV254 from [or] an infection by *M. tuberculosis* in a mammal, wherein the method compris[ing]es:

(A) preparing a biological sample containing cells of the mammal;

(B) incubating the biological sample with at least one product as defined in claim 11; and,

(C) detecting a cellular reaction indicating prior sensitization of the mammal to said product.

16. (Twice amended) A method for [the discriminatory detection of] discriminating [of the presence of] an antigen of *M. bovis* BCG[/], *M. bovis*, or *M. microti*

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OV254 [or] from an antigen of *M. tuberculosis* in a biological sample, wherein the method compris[ing]es:

(A) bringing the biological sample into contact with an antibody as claimed in claim 15; and

(B) detecting the antigen-antibody complex formed.

17. (Twice amended) A kit for [the discriminatory detection of] discriminating the presence of an antigen of *M. bovis* BCG[/], *M. bovis*, or *M. microti* OV254 [or] from an antigen of *M. tuberculosis* in a biological sample, wherein the kit compris[ing]es:

(A) an antibody as claimed in claim 15;

(B) reagents for constituting the medium suitable for the immunological reaction; and

(C) reagents allowing the detection of the antigen-antibody complexes produced by the immunological reaction.

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Washington, DC 20005
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Fax 202.408.4400
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